UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION **This Document Relates to All Actions**	MDL No. 2875 Honorable Robert B. Kugler, District Court Judge Honorable Joel Schneider, Magistrate Judge **ORAL ARGUMENT REQUESTED**

MANUFACTURER DEFENDANTS' REPLY BRIEF IN SUPPORT OF THEIR MOTION TO DISMISS

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INTRODUCTION

Plaintiffs' Consolidated Memorandum of Law in Opposition to Defendants' Motions to Dismiss (the "Opposition" or "Opp.")[1] relies upon broad characterizations, group allegations, and extrinsic materials in a gambit to persuade the Court to excuse manifest pleading defects and to postpone the culling of untenable claims until summary judgment.[2] Plaintiffs' position is that, because ***some*** Plaintiffs' claims may be viable against some Defendants under some states' laws, and ***all*** Plaintiffs' claims are lumped together in the Complaints into single counts, the Court is powerless to pare down Plaintiffs' pleadings at the dismissal stage.

Yet the very function of a motion to dismiss is to "test[] the legal sufficiency" of Plaintiffs' claims and "streamline[] litigation by dispensing with needless discovery and fact-finding[.]" *Mann v. Brenner*, 375 F. App'x 232, 239 (3d Cir. 2010) (quoting *Neitzke v. Williams*, 490 U.S. 319, 326–27 (1989)). That does not change in the MDL context. Plaintiffs' cases "retain their separate identities," and the Court is not at liberty to "disregard the [Federal] Rules' requirements" in

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[1] Unless otherwise defined, capitalized terms used herein have the meaning ascribed to them in Defendants' opening brief in support of their motion to dismiss, and Defendants expressly incorporate herein that brief and all of the attached compendia.

[2] Plaintiffs have also violated Local Rule 7.2(d) by submitting their Memorandum of Law in 12-point proportional font (Times New Roman) without reducing the page limits by 25 percent. The Court should thus disregard pages 91-108 of the Opposition.

assessing individual claims. *In re Nat'l Prescription Opiate Litig.*, 956 F.3d 838, 844–45 (6th Cir. 2020) (quoting *Gelboim v. Bank of Am. Corp.*, 574 U.S. 405, 413 & n.3 (2015)). Dismissing facially insufficient claims is not "piecemeal" merely because Plaintiffs have thrown multiple cases together into umbrella counts. The Court is still dismissing ***entire*** claims with respect to those Plaintiffs asserting them.[3]

It is not Defendants' obligation to "fire[]" a "silver bullet." Opp. 5. And Plaintiffs cannot satisfy their pleading obligations by referring the Court generically to the supposed "300+ pages of painstaking detail[,]" *id*. 3, in their Complaints, much less by directing the Court repeatedly to extrinsic materials, *id*. 13–14, 80 n.42, 91, 96–97. It is neither Defendants' nor the Court's job to sift through hundreds of pages of pleadings and extrinsic filings in search of the absent "short and plain statement" of Plaintiffs' claims. Fed. R. Civ. P. 8. Each Plaintiff must satisfy his or her individual standing requirement and plead legally sufficient claims against each Defendant within the four corners of the pleadings. Many have not met this obligation.

Dismissal of Plaintiffs' insufficient claims at this stage is not only the right

[3] MDL courts regularly dismiss insufficient claims by state. *See, e.g.*, *In re 100% Grated Parmesan Cheese Mktg. and Sales Pracs. Litig.*, 393 F. Supp. 3d 745, 765–66 (N.D. Ill. 2019) (on appeal); *In re Santa Fe Nat. Tobacco Co. Mktg. & Sales Pracs. Liab. Litig.*, 288 F. Supp. 3d 1087, 1276–77 (D.N.M. 2017); *In re Volkswagen Timing Chain Prod. Liab. Litig.*, No. 16-2765, 2017 WL 1902160, at *26 (D.N.J. May 8, 2017).

result, it is the desirable one. This Court can spare itself and the parties countless wasted hours and considerable squandered resources on discovery and fact-finding that is not just needless, but utterly pointless in the face of legally unsustainable claims. Pruning the Complaints now of uninjured Plaintiffs, deficient claims, and superfluous Defendants will better enable the Court and the parties to devote their time, attention, and resources to the much narrower subset of plausible claims. Given a choice between focusing on potentially meritorious clams or aimlessly churning meritless claims, Rule 12 is clear—the Court should dismiss the bad claims.

Defendants' opening brief and this reply identify with specificity the Plaintiffs who lack standing, the Defendants against whom no wrongs are alleged, and the claims that are preempted, intrude on FDA's primary jurisdiction, are subsumed by state product liability statutes, or fail to satisfy their requisite state elements. These Plaintiffs, Defendants, and claims should be dismissed.

BACKGROUND

I. THE OPPOSITION FAILS TO EXCUSE PLAINTIFFS' IMPROPER "SHOTGUN" PLEADING

A substantial portion of Plaintiffs' putative "Background" section is not background at all, but legal argument asserting that the Complaints are not "shotgun pleadings" because they "laboriously recount Defendants' manufacture and sale of adulterated VCDs[.]" Opp. 6, 19–21. It is the very "laborious[]" character of the Complaints that makes them "shotgun" pleadings. Each Master Complaint recites

400 to 450 paragraphs of prefatory allegations, followed by nine to eighteen claims, each of which generically incorporates by reference all of the preceding paragraphs, including each predecessor claim. And each claim is asserted against all Defendants.

Plaintiffs' Complaints are the definition of "shotgun" pleadings. In lieu of "a short and plain statement," the Complaints are "sprawling and inscrutable[.]" *Gov't Employees Ins. Co. v. Pennsauken Spine & Rehab P.C.*, No. 17-11727, 2018 WL 3727369, at *3 (D.N.J. Aug. 6, 2018) (Kugler, J.). Their incorporation of all previous paragraphs into each count is "a logarithmic expansion of paragraphs as each count incorporates previous incorporations that themselves incorporated incorporations." *Id*. Each count "thus snowballs into a blizzard of theories, facts, allegations, and claims which must be shoveled away" in search of a plausible dispute. *Id*. Plaintiffs' practice "is a far cry from Rule 8(c)'s requirement of 'short and plain statement.'" *Id*. (collecting cases). It is likewise "shotgun" pleading to lump all Defendants together in every count without giving "each defendant adequate notice" of the grounds for its alleged liability. *Theodore v. Newark Dep't of Health & Cmty. Wellness*, No. 19-17726, 2020 WL 1444919, at *3, 5 & n.3 (D.N.J. Mar. 25, 2020) (collecting cases). These impermissible pleading practices by themselves are sufficient to require dismissal. *See D'Addario v. Johnson & Johnson*, No. 19-15627, 2020 WL 3546750, at *6 (D.N.J. June 30, 2020).

II. THE OPPOSITION'S REQUEST FOR LEAVE TO AMEND IS IMPROPER

Plaintiffs' makeshift request for leave to amend, Opp. 7, fails because Plaintiffs did not "submit a draft amended complaint." *Fletcher–Harlee Corp. v. Pote Concrete Contractors, Inc.*, 482 F.3d 247, 252 (3d Cir. 2007).

III. THE OPPOSITION'S RELIANCE ON EXTRINSIC FACTS AND MATERIALS IS IMPERMISSIBLE

Plaintiffs repeatedly refer to putative facts and "illustrative" extrinsic materials, including: (i) dozens of previously unalleged assertions about Defendant Zhejiang Huahai Pharmaceutical Co., Ltd., Opp. 12–19; (ii) a letter brief (ECF 296) and its exhibits, filed months after the Complaints, *id*. 13–14, 80 n.42, 91, 96–97; and (iii) references to materials obtained in discovery, *id*. 20, 62, 67, 91. That invites error "because 'a court considering a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) may consider *only* the allegations contained in the pleading to determine its sufficiency.'" *In re Asbestos Prods. Liab. Litig. (No. VI)*, 822 F.3d 125, 133 (3d Cir. 2016) (quoting *Santomenno ex rel. John Hancock Trust v. John Hancock Life Ins. Co. (U.S.A.)*, 768 F.3d 284, 290 (3d Cir. 2014)) (emphasis in original).[4]

[4] The extrinsic statements and materials are set forth in the Compendium of Charts Referenced in the Manufacturer's Reply Brief. ("Second Charts") *See* Second Charts 1.

IV. THE OPPOSITION MISCHARACTERIZES ALLEGATIONS IN PLAINTIFFS' COMPLAINTS

Plaintiffs repeatedly cite allegations that fail to substantiate Plaintiffs' bare assertions.[5] The Court should disregard these "unsupported" statements. *Baraka v. McGreevey*, 481 F.3d 187, 211 (3d Cir. 2007) (citations omitted).

ARGUMENT

I. PLAINTIFFS FAIL TO MEET THEIR BURDEN OF ESTABLISHING STANDING ON BEHALF OF THE ELMC AND MMMC PLAINTIFFS

A. The ELMC Fails to Plead an Injury Under Article III

The Opposition does not dispute that the VCDs at issue provided the anticipated therapeutic benefit to the ELMC Plaintiffs, and does not contend Plaintiffs have suffered any concrete physical injury caused by the VCDs. The ELMC thus fails to allege Article III standing. *See, e.g.*, *In re McNeil Consumer Healthcare*, 877 F. Supp. 2d 254, 271 (E.D. Pa. 2012) (dismissing claims for lack of standing where "[n]o plaintiff alleges facts that" that would show the product "was actually defective as to them, *i.e.*, that it failed to perform as intended").

[5] *See, e.g.*, Opp. 9 (mischaracterizing allegation of link between NDMA and cancer), 10 (mischaracterizing allegations about ZHP), 12–13 (mischaracterizing allegations about manufacturing defendants); 18–19 (mischaracterizing allegations about manufacturing defendants), 19 (mischaracterizing allegations on manufacturer awareness), 67 (mischaracterizing allegations regarding indemnification agreements).

Lacking any therapeutic or physical harm, the ELMC Plaintiffs instead hunt for an economic injury. They assert the VCDs are "worthless," ELMC ¶ 359, and seek "to recoup the amounts that they paid[.]" Opp. 6. With no ***factual*** basis for this putative injury, Plaintiffs instead propose a ***legislative*** basis—the FDCA's prohibition on the sale of adulterated drugs—as a *per se* proxy for the VCDs being "worthless." *Id*. 23 (asserting adulterated VCDs are "unlawful to sell" and "consequently economically worthless"). Plaintiffs' proposed standard is legally deficient and ignores the indisputable benefits Plaintiffs actually received from the VCDs.

At the outset, Plaintiffs' invocation of the FDCA as the basis for their Article III standing confirms that their claims attempt to undertake private enforcement of the FDCA—and are therefore preempted. *See* § II.A, *infra*. The argument is also self-defeating, as Congress has made clear that violations of the FDCA are not cognizable as private injuries. *See* 21 U.S.C. § 337(a). "Article III standing requires a concrete injury even in the context of a statutory violation," and the judgment of Congress is "instructive and important" in identifying statutory violations that "constitute injury in fact." *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1549 (2016). Here, Congress has judged that sales of allegedly adulterated drugs are ***not*** actionable private injuries. 21 U.S.C. § 337(a). The fear of a "possible future injury"

from adulteration is "insufficient to satisfy" Article III. *Hubert v. Gen. Nutrition Corp.*, No. 15-01391, 2017 WL 3971912, at *5 (W.D. Pa. Sept. 8, 2017).

Plaintiffs' reliance on *Debernardis v. IQ Formulations, LLC*, 942 F.3d 1076 (11th Cir. 2019), is misplaced. *Debernardis* allowed for the possibility that allegations of adulterated supplements could "establish[] that the plaintiffs purchased a worthless product[,]" *id*. at 1087–88, but missed a critical point by omitting Section 337(a) of the FDCA from its analysis. The Eleventh Circuit jumped from FDA's ***public*** authority to keep adulterated dietary supplements off the market to a ***private*** injury without considering the FDCA's express prohibition on private enforcement under 21 U.S.C. § 337(a). *Id.* at 1080, 1085. Yet, "[a] plaintiff seeking to vindicate a public right embodied in a federal statute . . . must demonstrate that the violation of that public right has caused him a concrete, individual harm distinct from the general population." *Spokeo*, 136 S. Ct. at 1553 (Thomas, J., concurring). Here, with no physical injury or loss of efficacy, Plaintiffs have shown no injury "particular to [them]" to support private standing. *Id*.

Equally unavailing is Plaintiffs' reliance on cases in which plaintiffs alleged that they paid a "premium" or an "overpayment" for products based on false and deceptive sales practices. *See In re Gerber Probiotic Sales Pracs. Litig.*, No. 12-835, 2013 WL 4517994, at *5 (D.N.J. Aug. 23, 2013); *In re Mercedes-Benz Emissions Litig.*, No. 16-881, 2019 WL 413541, at *4 (D.N.J. Feb. 1, 2019), *cert. denied,* 2019

WL 2591158 (D.N.J. June 25, 2019), and *vacated and remanded,* 797 F. App'x 695 (3d Cir. 2020). Plaintiffs allege no facts indicating such a premium or overpayment here.

In fact, Plaintiffs assert the opposite theory—that their VCDs ***lost*** 100% of their value. But as the Third Circuit made clear in *In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Pracs. & Liab. Litig.*, 278 (3d Cir. 2018), a claim based on loss of value requires that Plaintiffs "failed to receive the benefit of their bargains[.]" *Id*. at 290 n.14 (distinguishing *Kwikset Corp. v. Superior Court*, 246 P.3d 877 (Cal. 2011)). Plaintiffs do not allege their VCDs injured them or were any less effective due to the presence of nitrosamines, and thus fail to allege that their VCDs provided "an economic benefit worth one penny less" than what they paid. *Id.* at 288. Standing requires Plaintiffs to do more than "simply characterize [their] purchases as economic injuries"; such claims are "nothing more than mere conjecture" without a basis in fact. *Id*. at 281, 290–92. Plaintiffs' "wish to be reimbursed for a functional product" they already used "without incident" is not "an economic injury within the meaning of Article III." *Id*. at 293.

B. The MMMC Fails to Plead an Injury Under Article III

The MMMC Plaintiffs also fail to allege a concrete injury. The MMMC's allegation that exposure may give rise to future potential health consequences is exactly the type of "abstract or conjectural or hypothetical" injury routinely held to

be insufficient to confer standing. *Danvers Motor Co. v. Ford Motor Co.*, 432 F.3d 286, 291 (3d Cir. 2005) (quoting *Raines v. Byrd,* 521 U.S. 811, 819 (1997)). Plaintiffs' summary assertion of sufficient injury, Opp. 31, does not overcome this governing principle, and their authorities fall short because they require more than the mere potentiality of future health concerns to demonstrate injury in the medical monitoring context. *See Reilly v. Ceridian Corp.*, 664 F.3d 38, 45 (3d Cir. 2011) (requiring monies already have been expended on medical monitoring); *Player v. Motiva Enters., LLC*, No. 02-3216, 2006 WL 166452, *9–10 (D.N.J. Jan. 20, 2006) (Kugler, J.) (not examining standing and requiring a "significant" risk of serious disease); *Fried v. Sungard Recovery Servs.*, 925 F. Supp. 375, 377 (E.D. Pa. 1996) (requiring physical manifestation of asymptomatic pleural thickening to support medical monitoring under Pennsylvania law in asbestos exposure cases).[6]

[6] Plaintiffs' response regarding personal jurisdiction underscores the need that these issues be determined now. Plaintiffs have no answer to the fact that they do not allege a jurisdictional-predicate purchase in New Jersey vis-à-vis numerous out-of-state defendants. Instead, they cite an inapposite decision regarding standing to assert claims on behalf of absent class members. Nor can they absolve their jurisdictional defects by merely implying personal jurisdiction existed in unspecified transferor courts. Even if the Court were to look at transferor court jurisdiction for those limited named plaintiffs and defendants to which the argument might apply (and it should not), it would still find alleged purchases lacking. So too with respect to those foreign defendants who may not be joined in litigation in the United States simply because a domestic affiliate may operate here. These threshold jurisdictional deficiencies are determinable now on the pleadings, and Defendants respectfully submit that they should be permitted to brief them on the merits.

C. The Injuries Alleged in the ELMC and MMMC Are Not Traceable to Each Defendant

The Opposition duplicates the deficiencies of the ELMC and MMMC by lumping Defendants together and asserting all Plaintiffs' injuries are traceable to all Defendants collectively. Opp. 32–39. But it is a bedrock principle of standing that Plaintiffs cannot maintain an action—individually or as class representatives—against Defendants to whom no Plaintiff's injury has been traced. *See, e.g.*, *In re Franklin Mut. Funds Fee Litig.*, 388 F. Supp. 2d 451, 461 (D.N.J. 2005) (requiring that "at least one named plaintiff" must establish "injury traceable" to "each named defendant"); *Clark v. McDonald's Corp.*, 213 F.R.D. 198, 223 (D.N.J. 2003); *see also* 1 Newberg on Class Actions § 2:5 (5th ed.) ("In multidefendant class actions, the named plaintiffs must show that each defendant has harmed at least one of them.").

Plaintiffs have failed to trace their injuries to more than 25 manufacturer, wholesaler, and pharmacy Defendants.[7] *See* Charts 10–11. The Opposition does not even attempt to address this threshold pleading failure, blithely asserting instead that

[7] Plaintiffs are incorrect to imply that this argument was made by the manufacturer defendants alone. *See* Opp. 32. As directed by the Court, all Defendants collectively briefed the Court across multiple issues and parties without unnecessary overlap among the briefs, and each defendant group incorporated and adopted arguments contained in the other briefs by reference. *See* ECF 520-3 at 2 n.4; ECF 522-1 at 3; ECF 523-1 at 4 & n.4. It is for this reason that Charts 10–11 list each of the defendants subject to dismissal on these grounds.

such concerns are "for another day" through the inclusion of "additional plaintiffs." Opp. 32 n.4. But putative class representatives "must meet Article III standing requirements the moment a complaint is filed." *Neale v. Volvo Cars of N.A., LLC*, 794 F.3d 353, 367 (3d Cir. 2015); *see also Ponzio v. Mercedes-Benz USA, LLC*, 447 F. Supp. 3d 194, 222 (D.N.J. 2020) (same). Plaintiffs' concession that they did not and cannot now meet those requirements for more than two dozen Defendants named in the ELMC and MMMC is dispositive and requires dismissal.

Plaintiffs' sole authority for their claim that it is unnecessary "for a class to have a representative against every defendant[,]" Opp. 32 n.4, says nothing of the kind. It merely recognizes that plaintiffs who "indisputably have standing to litigate their own claims" are not impeded from litigating "materially identical claims" as class representatives. *In re Asacol Antitrust Litig.*, 907 F.3d 42, 47 (1st Cir. 2018). That has nothing to do with suing Defendants to whom no injury has been traced.

Accordingly, the claims against Defendants identified in Charts 10–11 should be dismissed because they lack the traceability required to establish standing.

D. Plaintiffs Lack Standing to Bring State Law Claims in States Where They Do Not Allege Injury

The Opposition contends that the ELMC and MMMC Plaintiffs can assert claims as putative class representatives under the laws of states and territories in which they do not reside and were not injured. Opp. 38–39. But Plaintiffs erroneously rely on precedent holding that a putative class representative is not

obliged to establish the standing of ***unnamed*** class members. *See Neale*, 794 F.3d at 362; *Rolland v. Spark Energy, LLC*, No. 17-2680, 2019 WL 1903990, at *5 n.6 (D.N.J. Apr. 29, 2019) (citing *Langan v. Johnson & Johnson Consumer Cos., Inc.*, 897 F.3d 88, 96 (2d Cir. 2018)).[8]

Even accepting that premise, the ***named*** Plaintiffs must still "demonstrate standing for each claim [they] seek[] to press[.]" *DaimlerChrylser Corp. v. Cuno*, 547 U.S. 332, 352 (2006). That means they must "establish standing for each claim asserted in the complaint[,]" and "lack standing to assert claims on behalf of unnamed plaintiffs in jurisdictions where [p]laintiffs have suffered no alleged injury." *Ponzio v. Mercedes-Benz USA, LLC*, 447 F. Supp. 3d 194, 222–23 (D.N.J. 2020). In *Ponzio*, this Court rejected the same argument pressed here and dismissed plaintiffs' multi-state and nationwide state law claims outside of the states represented by named plaintiffs. *Id*. at 223. The same result should obtain here. "Otherwise, a plaintiff would be able to bring a class action complaint under the laws of nearly every state in the Union without having to allege concrete, particularized injuries relating to those states, thereby dragging defendants into expensive

[8] *Mielo v. Steak N' Shake Operations, Inc.*, 897 F.3d 467 (3d Cir. 2018) and *Rolland* cited by plaintiffs are inapposite to the case here. *Mielo* addresses class representatives' ability to bring a uniform *federal statutory claim* under the Americans with Disabilities Act. *Mielo*, 897 F.3d at 481–82. *Rolland* deals with a single named plaintiff, representing only a potential theoretical multistate class, who alleged injury stemming from a single defendant's actions in New Jersey.

nationwide class discovery, potentially without a good-faith basis." *In re Magnesium Oxide Antitrust Litig.*, No. 10-5943, 2011 WL 5008090, at *10 (D.N.J. Oct. 20, 2011).

II. THE OPPOSITION FAILS TO OVERCOME PREEMPTION AND PRIMARY JURISDICTION

A. Most of Plaintiffs' Claims Are Preempted

Plaintiffs' Opposition asserts: (1) impossibility preemption is inapplicable because it was possible for Defendants to comply with both federal and state law, Opp. 40–42, and (2) implied preemption is inapplicable because Plaintiffs' claims have an independent basis in state law, *id.* 42–45. The first point attacks an argument Defendants have not made. The second point is unsupported as a matter of law and at odds with Plaintiffs' entire theory of this case.[9]

1. Plaintiffs' Arguments Against Impossibility Preemption Are Irrelevant

Plaintiffs elevate an imagined argument to first position in their brief by contesting "impossibility preemption." Opp. 40–42. But Defendants have not argued

[9] Plaintiffs also assert preemption is an affirmative defense unsuited to a motion to dismiss. Opp. 39–40. That is incorrect. The seminal case on implied preemption under Section 337(a) applied it on a motion to dismiss. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 347 (2001). Plaintiffs rely on a footnote in a Third Circuit opinion that reversed a district court's preemption decision for relying on "facts that were neither in [the] complaint nor undisputed." *In re Asbestos Prods. Liab. Litig. (No. VI)*, 822 F.3d 125, 128, 133 n.6 (3rd Cir. 2016). Yet the same footnote acknowledges that a motion to dismiss is appropriate when, as here, "preemption is manifest in the complaint itself." *Id.* at 133 n.6 (citations omitted).

that doctrine. In light of the Complaints' ambiguity, Defendants simply reserved the issue "to the extent" Plaintiffs intended to allege—but failed to articulate—that Defendants had a state-law obligation to alter labels or manufacturing processes to comply with state law. *See* ECF 520-3 (hereinafter "Br.") 24 n.22, 38–39 n.35. Defendants' ability or inability to comply with both federal and state law is irrelevant to the actual preemption question before this Court—whether Plaintiffs are pursuing impermissible private enforcement of the FDCA.

2. Plaintiffs' Arguments Against Implied Preemption Are Contrary to Plaintiffs' Own Allegations and Arguments Elsewhere in the Same Opposition

As to implied preemption, the Opposition asserts it is a "narrow defense" limited to "fraud-on-the-FDA claims." Opp. 42. But it is not so circumscribed. Though *Buckman* itself involved a fraud-on-the-FDA claim, its effect is to preempt all "private proceedings that rely on alleged violations of the FDCA as a necessary component of their cause of action and that seek to redress or restrain those FDCA violations." Corrected Brief for the United States as Amicus Curiae Supporting Appellee at 10–11, *Amarin Pharma, Inc. v. ITC* (Fed. Cir. Mar. 27, 2018) (2018-1247, 2018-114) ("FDA Amicus") (quoting 21 U.S.C. § 337(a)). Anything less fails to give "meaningful effect" to the bar on private enforcement. *Id.*; *see also Excela Pharma Sciences, LLC v. Sandoz Inc.*, ---F. Supp. 3d.---, No. 19-318, 2020 WL 5535026, at *5 (W.D.N.C. Sept. 15, 2020) (citation omitted) (holding FDCA's

"prohibition on private actions . . . would be 'thwarted if savvy plaintiffs can label as arising under a state law . . . a claim that in substance seeks to enforce the FDCA'"). FDA's views on the preemptive scope of Section 337(a)—which the Opposition does not even mention—are "significant" and deserving of deference. *Horn v. Thoratec Corp*., 376 F.3d 163, 170–71 (3d Cir. 2004).[10]

Plaintiffs next claim that they do not seek to enforce the FDCA because their claims are based on "independent state law[.]" Opp. 42. That ignores Plaintiffs' own allegations expressly predicated on FDCA and FDA regulatory violations, such as:

- Defendants sold or manufactured "adulterated drugs"—drugs that are, *inter alia*: non-compliant with cGMPs, 21 U.S.C. § 351(a)(1); different from their approved brand-name counterpart, *see id*. § 351(b); or mixed with a substance that reduces their quality, *see id*. § 351(d); and

- Defendants sold a drug that was not the "same" as the brand-name in violation of the "duty of sameness" of generic drugs, *id.* § 355(j)(2)(A)(i)–(v), and drug labeling, *see id*. § 321(m).

Plaintiffs do not contest that each claim at issue relies on proving either ***conduct*** that violated the FDCA or ***false statements*** about compliance with the FDCA. *See* Br. 21–27. These claims are preempted because, "though nominally brought under [state law]," they "attempt to enforce or restrain violations of the

[10] Defendants also rely on the Solicitor General's representations as to the preemptive scope of Section 337(a), *see* Br. 19 n.15 (citing Brief of Federal Respondent ITC in Opposition at 12, *Amarin Pharma, Inc. v. ITC*, (No. 19-152) (Nov. 4, 2019), 2019 WL 5784708, at *12)). Plaintiffs do not address that authority, either.

FDCA[,]" and seek as a "necessary component" to "prove FDCA violations and compel obedience to the FDCA through the remedies provided by [state law]." FDA Amicus at 1. The analysis is straightforward; it asks whether Plaintiffs' claims could proceed in the absence of the FDCA's requirements. The negligence *per se* and design defect claims could not because the FDCA supplies the standards of conduct Defendants allegedly violated. And the breach of express warranty, fraudulent misstatement, negligent misstatement, and state consumer protection law claims could not, as Defendants' purported misstatements are only false because Defendants allegedly misrepresented compliance with the FDCA.[11]

The Opposition itself further illustrates Plaintiffs' reliance upon the FDCA. It is littered with citations to the FDCA, statements referring to Defendants' VCDs as "adulterated [and] misbranded," and references to Defendants' alleged actions as "unlawful" and in violation of the FDCA. *See, e.g.*, Opp. 2, 12, 19. Plaintiffs' entire theory of this case is based on Defendants' supposed failure to comply with the FDCA's prohibition on the manufacture and sale of adulterated drugs, including alleged non-compliance with the cGMPs and the FDCA's "sameness" requirements, not (unidentified) "analogous state law." *Id.* 23.

Plaintiffs' further assertion (without citation) that their claims "are traditional

[11] Plaintiffs' reliance on the FDCA distinguishes this case from Plaintiffs' principal authority, *In re Reglan Litig.*, 142 A.3d 725, 739 (N.J. 2016). The failure-to-warn claims there were not "dependent on" federal law. *Id.*

state law claims" that do not "conflict with, or pose an obstacle to, compliance with federal requirements," *Id.* 44–45, conflates implied preemption under the FDCA with impossibility preemption and/or obstacle preemption. Whether labeled "traditional" or not, "private litigants may not bring a state-law claim against a defendant when the state-law claim is in substance (even if not in form) a claim for violating the FDCA." *Excela Pharma Sciences*, No. 19 -00318, 2020 WL 5535026, at *5 (internal quotations and citation omitted).

Oddly, the only two claims Plaintiffs even attempt to defend by name against preemption are negligence, Opp. 43, and manufacturing defect, *id.* 44. Defendants did not argue either claim is preempted altogether—just limited to theories deriving from independent state-law duties. *See* Br. 22 n.19, 44. As for the remaining claims, rather than address Defendants' claim-by-claim preemption analysis, Plaintiffs simply assert in broad strokes that their "claims have an independent state law basis, and Plaintiffs explicitly do not seek to enforce FDA regulations as the sole basis for recovery[,]" followed by string citations to the Complaints. Opp. 42–43. Plaintiffs cannot so easily dispense with their own allegations. They chose to frame their claims by reference to and in express reliance upon alleged FDCA violations, intruding upon enforcement committed "exclusively to the federal government to ensure that complex enforcement decisions are made with the benefit of FDA's scientific and regulatory expertise." FDA Amicus at 7.

B. The Primary Jurisdiction Doctrine Requires Abstention from Plaintiffs' Claims

The Opposition constructs a strawman in place of Defendants' actual primary jurisdiction argument, insisting Defendants seek to interpose primary jurisdiction as an absolute bar to all cases involving FDA-regulated products. Opp. 45. That has never been Defendants' position. Primary jurisdiction is implicated only where "protection of the integrity of a regulatory scheme dictates preliminary resort to the agency which administers the scheme." *Clark v. Actavis Grp. hf*, 567 F. Supp. 2d 711, 715 (D.N.J. 2008) (quoting *Cheyney State Coll. Faculty v. Hufstedler*, 703 F.2d 737, 736 (3d Cir. 1983) (internal citation omitted)). The Opposition relies on Ninth Circuit authority to suggest that primary jurisdiction is limited to issues of "first impression" and "particularly complicated issue[s.]" Opp. 46 (citing *Astiana v. Hain Celestial Grp., Inc.*, 783 F.3d 753, 760 (9th Cir. 2015)). Though both are present here, there is no indication the Third Circuit has confined primary jurisdiction to those two circumstances. To the contrary, primary jurisdiction "may even be applied 'in cases where the [issues] raised are within the ordinary experience of [the] judiciary.'" *Clark*, 567 F. Supp. 2d at 715 (quoting *IPCO Safety Corp. v. WorldCom, Inc.,* 944 F. Supp. 352, 355 (D.N.J. 1996) (internal citation omitted)).

For the first of the four factors used to decide primary jurisdiction—specialization—Plaintiffs do not dispute that their allegations raise numerous issues within FDA's specialized expertise. *See* Br. 28–29 (listing specialized topics). But

the Opposition insists that "liability" issues are "well within the conventional experience" of the Court. Opp. 46. While that may be true of the general topic of "liability," to get to a liability determination here, the Court must first wade through questions of bioequivalence, pharmacokinetic profiles, A/B ratings, Orange Book listings, cGMPs, FDA standards, and FDA labeling. These are not the everyday matters of conventional judicial experience.

With respect to the second factor—agency discretion—Plaintiffs assert FDA has "already made" its "initial determination" that Defendants' VCDs contained unsafe levels of nitrosamines and insists any remaining issues "do not fall within an agency's discretion." Opp. 46–47. The Complaints contain no allegations of such a "determination" by FDA. Plaintiffs allege limited FDA testing results (with more to come) and allege recalls to date are just the "tip of the iceberg." *See, e.g.*, PIMC ¶¶ 8, 10, 170–82, 284–85, 391; ELMC ¶¶ 5, 241–42, 312, 346–50, 405; MMMC ¶¶ 4, 203, 313–16, 381. Nothing suggests FDA has completed its discretionary work.

Indeed, FDA has only just issued its first guidance to industry on this topic. *See* FDA, *Control of Nitrosamine Impurities in Human Drugs: Guidance for Industry* (September 2, 2020) (the "Guidance") (available at https://www.fda.gov/media/141720/download) (last accessed Sept. 13, 2020).[12] The Guidance makes

[12] The Court may take judicial notice of FDA's public records. *Otsuka Pharm. Co. v. Torrent Pharm. Ltd., Inc.*, 118 F. Supp. 3d 646, 655 n.7 (D.N.J. 2015).

clear this is a complicated issue and one of first impression in which FDA continues to exercise discretion. FDA has already seen voluntary recalls lead to drug shortages, "continues to investigate[,]" and has partnered with other regulatory authorities "to share information, coordinate inspection efforts, communicate effective analytical methods to detect and identify various nitrosamines, and to develop rapid solutions to ensure the safety and quality of the drug supply." *Id*. at 2–3.

Plaintiffs concede the last two factors—danger of inconsistent rulings and prior application to the agency. All four factors in this case thus weigh in favor of abstention on primary jurisdiction grounds, distinguishing this case from Plaintiffs' authorities. *See Baykeeper v. NL Indus., Inc.*, 660 F.3d 686, 691–92 (3d Cir. 2011) (finding all four factors weighed against primary jurisdiction); *Bus. Edge Grp., Inc. v. Champion Mortg. Co.*, 519 F.3d 150, 154 (3d Cir. 2008) (finding primary jurisdiction unnecessary for question of textual interpretation). The Court should abstain from Plaintiffs' remaining claims on primary jurisdiction grounds.

III. THE NJPLA AND OTHER STATE PLAS SUBSUME MOST OF PLAINTIFFS' CLAIMS

A. The ELMC Claims Are Subsumed

Plaintiffs' assertions about *Sun Chem. Corp. v. Fike Corp*., 235 A.3d 145 (N.J. 2020), Opp. 49–50, are wrong. In *Sun Chemical*, the New Jersey Supreme Court answered the narrow question of whether a New Jersey Consumer Fraud Act ("CFA") claim "may be brought in the same action as a PLA claim[.]" 235 A.3d at

148.[13] To the extent *Sun Chemical* relates to this action at all, it carefully explains the Court's previous holding in *Sinclair v. Merck & Co.*, 948 A.2d 587 (N.J. 2008), and reaffirms Defendants' central thesis here—a CFA claim and other causes of action are subsumed where "plaintiffs' allegations" demonstrate that "[t]he heart of [their] case [was] the potential for harm caused by" a defendant's drug. *Sun Chem.*, 235 A.3d at 154 (quoting *Sinclair*, 948 A.2d at 596) (alterations in original). Plaintiffs' "failure to allege physical injuries" in the ELMC does not remove its claims from the purview of the NJPLA. *Id.* Nor do claims for pure economic loss avoid the NJPLA where, as here, that loss is measured by the presence of a purportedly dangerous, carcinogenic impurity. *See* Br. 34–35 (citing *Levinson*; *Crouch*; *Boyd*).[14] Plaintiffs' theory of harm emphasizes economic loss *because* of

[13] Contrary to Plaintiffs' assertion, Opp. 49, nothing about *Sun Chemical* suggests that New Jersey has now decided to deviate from the long line of cases demonstrating that product liability claims are subsumed. Moreover, Plaintiffs' insinuation that "only" manufacturing defect, design defect, and failure-to-warn claims are subsumed, Opp. 49, is a misunderstanding of NJPLA jurisprudence. As Judge Kugler previously stated, "The PLA is 'both expansive and inclusive, encompassing virtually all possible causes of action relating to harms caused by consumer and other products.'" *Sich v. Pfizer Pharm.*, No. 17-02828, 2017 WL 4407930, at *2 (D.N.J. Oct. 4, 2017) (finding claims for strict products liability, negligence, breach of implied warranty, and loss of consortium subsumed by NJPLA) (quoting *In re Lead Paint Litig.*, 924 A.2d 484, 436–37 (N.J. 2007)).

[14] *Levinson v. Johnson & Johnson Consumer Cos., Inc.*, No. 09-3317, 2010 WL 421091 (D.N.J. Feb. 1, 2010), *reconsidered on other grounds*, 2010 WL 3024847 (D.N.J. Aug. 2, 2010) (dismissing complaint); *Crouch v. Johnson & Johnson Consumer Co., Inc.,* No. 09-2905, 2010 WL 1530152 (D.N.J. Apr. 15, 2010) *reconsidered on other grounds*, 2010 WL 3024692 (D.N.J. Aug. 2, 2010); *Boyd v. Johnson & Johnson Consumer Co., Inc.,* No. 09-3135, 2010 WL 2265317 (D.N.J.

the potential danger of an alleged impurity, so Plaintiffs' claims—including their CFA claims—are subsumed by the NJPLA.

Although Plaintiffs list a number of states with "economic loss" exceptions in their charts, they concede that the "analysis and principles" of the NJPLA should apply "equally to any of the other states' product liability acts[.]" Opp. 49; *see also* Charts 16–19. In this respect, measuring economic loss via carcinogenic properties subsumes Plaintiffs' claims within the scope of other PLAs. *See* ELMC ¶ 362.

B. The MMMC Claims Are Subsumed

Plaintiffs state the MMMC alleges the type of injury encompassed by the NJPLA, so their claims are subsumed. Opp. 51. Although Defendants do not concede cellular damage and genetic harm constitute physical harm, *see Parker v. Wellman*, 230 Fed. App'x. 878 (11th Cir. Apr. 18, 2007), *Sinclair* squarely addresses why claims premised on medical monitoring are subsumed by the NJPLA even where those claims do not allege a compensable physical injury. *Sinclair*, 948 A.2d at 589.[15] Plaintiffs fail to distinguish *Sinclair*. The NJPLA subsumes their claims, and the MMMC should be dismissed for all states with PLAs. *See* Charts 16–19; *see also Clements v. Sanofi-Aventis, U.S., Inc.*, 111 F. Supp. 3d 586, 596 (D.N.J. 2015)

May 31, 2010) (same) *reconsidered on other grounds*, 2010 WL 3024845, at *6 (D.N.J. Aug. 2, 2010) (dismissing complaint).

[15] Plaintiffs do not appear to separately address the NJPLA or other PLAs as they relate to PIMC claims. For reasons already stated, those claims are subsumed, and Plaintiffs have not contested their dismissal.

(holding the NJPLA subsumes "any cause of action 'for harm caused by a product'") (quoting N.J.S.A. § 2A:58C–1(b)(3)).

IV. THE OPPOSITION CANNOT SALVAGE ALL OF PLAINTIFFS' STATE LAW CLAIMS

A. Defendants Do Not Seek "Piecemeal" Dismissal

Plaintiffs attempt to leverage the structure of the Complaints—in which all Plaintiffs and Defendants, and all states' laws, are thrown together into umbrella counts organized by one legal theory—to prevent dismissal of ***any*** Plaintiff's claims unless an argument can be applied globally to ***every*** Plaintiff's claim. It is entirely appropriate for the Court to dismiss individual Plaintiffs' claims where those Plaintiffs cannot satisfy their pleading obligations under the state law governing those claims, even if other individual Plaintiffs' claims under the same theory might survive under their states' laws.

Individual cases in an MDL "retain their separate identities" and must continue to be assessed separately under the Federal Rules. *In re Nat'l Prescription Opiate Litig.*, 956 F.3d at 844 (quoting *Gelboim*, 135 S. Ct. at 904 & n.3). Accordingly, the Complaints' counts do not represent single claims, but amalgamations of multiple Plaintiffs' claims against multiple Defendants, each of which retains its identity and is subject to separate consideration and dismissal.

"Piecemeal" dismissal is something else altogether—the dismissal of part but not all of a single claim. That is, the dismissal of specific allegations while the claim

survives. *See, e.g.*, *BBL, Inc. v. City of Angola*, 809 F.3d 317, 325 (7th Cir. 2015) (stating "Rule 12(b)(6) doesn't permit piecemeal dismissals of ***parts*** of claims") (emphasis in original). As Plaintiffs' own authority acknowledges, Rule 12(b)(6) "is the proper procedural mechanism to dismiss part of a complaint[.]" *Redwind v. W. Union, LLC*, No. 18-02094, 2019 WL 3069864, at *4 (D. Or. June 21, 2019). "Rule 12(b)(6) provides for the dismissal of a complaint, ***in whole or in part***, if it fails to state a claim upon which relief can be granted." *Thompson v. Real Est. Mortg. Network, Inc.*, 106 F. Supp. 3d 486, 489 (D.N.J. 2015) (emphasis added). Defendants have identified fatal defects of law in entire claims brought by multiple Plaintiffs under the governing laws of multiple states. Preserving facially untenable claims serves no interest of justice or efficiency, and is directly contrary to the narrowing function of Rule 12(b)(6). *See Mann*, 375 F. App'x at 239.

B. Plaintiffs Fail to Plead Breach of Warranty Claims

1. Plaintiffs' Implied Warranty Claims Fail[16]

a. The Implied Warranty Claims in the ELMC and MMMC Fail to Allege Injury or Loss of Functionality

Where a product performs its ordinary or general purpose, no breach has occurred. Br. 46. Contrary to Plaintiffs' suggestion, Opp. 54–55, the implied warranty of merchantability *does not* guarantee that the "goods [at issue] precisely fulfill" a buyer's "expectation." *Lieberson v. Johnson & Johnson Consumer Cos.,*

[16] For reasons stated above, Plaintiffs' implied warranty claims are preempted.

Inc., 865 F. Supp. 2d 529, 542 (D.N.J. 2011). Rather, the warranty provides for a "minimum level of quality," and assures "the product sold should be of the *general* kind described and reasonably fit" for its "***general***" purpose. *Id.* (internal citations and quotation marks omitted) (emphasis added). In other words, breaching the implied warranty requires loss of functionality or physical harm. *See* Br. 46.

Plaintiffs cite exactly one case, *Debernardis*, which does not even involve an implied warranty claim. Opp. 55–56. Plaintiffs fail to cite any authority showing that a breach of implied warranty claim survives where the product delivered its promised therapeutic benefits and did not harm consumers. Plaintiffs' efforts to distinguish Defendants' authorities also fail. Opp. 56–57. These cases illustrate that a product does not violate the implied warranty of merchantability simply because it contains a small amount of a toxic substance (*Hoffman*), incorporates undisclosed ingredients (*Hammer*), or was counterfeit (*Bowman*). Br. 46–47.[17]

The Complaints allege the implied warranty laws of the fifty states reflect the UCC. MMMC ¶ 459; ELMC ¶ 459. And numerous jurisdictions, similar to New Jersey, have found implied warranty claims unavailable in the absence of injury or

[17] *Hoffman v. Nutraceutical Corp.*, No. 12-5803, 2013 WL 2650611, at *4 (D.N.J. June 10, 2013); *Hammer v. Vital Pharms., Inc.*, No. 11-4124, 2012 WL 1018842, at *12 (D.N.J. Mar. 26, 2012); *Bowman v. Ram Med., Inc.*, No. 10-4403, 2012 WL 1964452, at *5 (D.N.J. May 31, 2012).

loss of functionality.[18] Because Plaintiffs have not pointed to a divergence of law with respect to the arguments raised in Defendants' Motion to Dismiss, the Court may use New Jersey law at this stage to evaluate the implied warranty claims of all states and to dismiss all claims. *See, e.g.*, *Ciecka v. Rosen*, 908 F. Supp. 2d 545, 552 (D.N.J. 2012) (citations omitted) (if "no conflict, the forum state's law applies.").

b. Plaintiffs' Alleged Privity Exceptions Are Inapplicable

Plaintiffs attempt to identify various exceptions to the privity requirement in a handful of states, Opp. 68–70, but they appear to concede that at least eight states require privity for breach of implied warranty and no exception applies.[19] To the extent these states may recognize exceptions to the privity requirement, Plaintiffs have not briefed or explained those exceptions. For the remaining states, Plaintiffs list several inapplicable purported exceptions. *Id.* 68–70.

First, Plaintiffs identify Florida, Georgia, Illinois, and Vermont as states creating an exception to privity for implied warranties, but Plaintiffs either misconstrue the case law or the scope of the exception in those states.[20] *Id.* 68.

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[18] A non-exhaustive list can be found at Second Charts at 6. New Jersey is not unique in its interpretation of the implied warranty of merchantability.

[19] AZ, ID, IA, KA, KY, MI, OR, TN, and WI.

[20] **Florida**: the exception applies only where there is "*direct* contact by means of actual one-on-one communication[,]" which is not at issue here. *Toca v. Tutco, LLC*, 430 F. Supp. 3d 1313, 1326 (S.D. Fla 2020) (emphasis in original); **Georgia**: the case cited by Plaintiffs muddles the difference between express and implied warranties, and a subsequent case clarified, "[i]t is settled Georgia law that manufacturers may not be subject to implied warranty liability because of the lack

Next, Plaintiffs assert that Alabama, Nevada, North Carolina, Ohio, Utah, and Washington have adopted the third-party beneficiary doctrine. *Id.* 69. But, Plaintiffs are not third-party beneficiaries. To be a beneficiary, a third party's identity must be known to the defendant and the purported contract must be entered with the clear contemplated purpose of directly benefiting the third party. *See Traxler v. PPG Indus.*, 158 F. Supp. 3d 607, 624–27 (N.D. Ohio 2016) (interpreting Ohio, North Carolina, New York, and Washington law); *see also Ironshore Specialty Ins. Co. v. Callister, Nebeker & McCullough*, No. 15-677, 2016 WL 633353, at *6–7 (D. Utah Feb. 17, 2016); *Stinson v. Twin Pines Coal, Co.*, No. 14-334, 2014 WL 4472605, at *5–6 (M.D. Ala. Sept. 11, 2014); *McVay v. Allied World Assur. Co., Inc*, 16 F. Supp. 3d 1202, 1207 (D. Nev. 2014). "Incidental" (as opposed to "direct") beneficiaries of downstream consumer transactions fall outside the exception. *See Traxler*, 158 F. Supp. 3d at 624–27. Conclusory allegations that a plaintiff is a third-party beneficiary cannot survive a motion to dismiss. *See id.*

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of privity between the manufacturer and the ultimate product purchaser . . . there are no exceptions to this rule." *Morgan v. Dick's Sporting Goods, Inc*., 359 F. Supp. 3d 1283, 1292 (N.D. Ga. 2019) (citing *Lee v. Mylan Inc.*, 806 F. Supp. 2d 1320 (M.D. Ga. 2011); **Illinois**: Plaintiffs cite two cases. In *McDonald's*, Plaintiffs did not even bring a breach of implied warranty of merchantability claim. In *Canadian Pacific*, the purported exception requires a manufacturer to know the "identity" of the consumer, which is not at issue here. No. 02 C 8800, 2005 WL 782698, *12 (N.D. Ill. Apr. 6, 2005); **Vermont**: Plaintiffs inexplicably cite *Moffit*, which only concerns lack of privity in property damage cases. *Moffit* does not suggest that privity is relaxed in implied warranty economic loss cases. 407 F. Supp. 2d at 598.

Lastly, Plaintiffs state that New York and Connecticut have privity exceptions for foodstuffs or pharmaceuticals, but these exceptions do not apply.[21] Opp. 70.

2. Plaintiffs' Express Warranty Claims Fail

a. Plaintiffs Have Not Demonstrated How Any Express Warranty Became the Basis for Any Bargain

Plaintiffs argue they have met the "basis of the bargain" requirement, but cite no authority for their mistaken view of what comprises a "basis of the bargain." Opp. 62–63. The fact that a medication leaflet or other alleged warranty must legally accompany the sale of a medication does not, by itself, meet the basis of the bargain requirement, as the alleged warranty must be seen or heard by the purchaser.[22] Br. 46-47. *Metcalfe v. Biomet, Inc.*, No. 18-456, 2019 WL 192902, at *4 (D.N.J. Jan. 15, 2019) ("[I]f a plaintiff does not plead that he saw the alleged warranty, then a court cannot *reasonably* infer that the warranty formed a basis of the bargain.")

[21] **New York**: The New York case cited by Plaintiffs predates New York's enactment of the UCC and does not apply. *Weisblum v. Prophase Labs, Inc.*, 88 F. Supp. 3d 283 (S.D.N.Y. 2015). There is no modern articulated exception for foodstuffs or pharmaceuticals. *See id.* **Connecticut:** Connecticut law requires a plaintiff to rely on a manufacturer's representations, or at least see the warranty, to void the privity requirement for the implied warranty, and there are no such allegations here. *See 100% Grated Parmesan Cheese*, 393 F. Supp. 3d at 760 (interpreting Connecticut law).

[22] Plaintiffs claim that simply calling the medication "valsartan" also creates an express warranty is belied by the ample precedent demanding specificity for express warranties. S*ee* Br. 48.

(emphasis in original); *In re: Elk Cross Timbers Decking Mktg.*, No. 15-18, 2015 WL 6467730, at *28 (D.N.J. Oct. 26, 2015) (interpreting multiple states' law).

Plaintiffs also conflate "reliance" with "basis of the bargain." Opp. 63. Although *some* jurisdictions apply a reliance requirement,[23] at a minimum, "basis of the bargain" still compels plaintiffs to plead that they have "read, seen, or heard the advertisements at issue." *Ciopollone v. Liggett Grp., Inc.*, 893 F.2d 541, 569 (3d Cir. 1990), *rev'd in part on other grounds,* 505 U.S. 504 (1992). Defendants' Charts at 39–41 demonstrate that "basis of the bargain" remains a statutory requirement for jurisdictions adopting the UCC. Plaintiffs cannot satisfy this requirement.

b. Plaintiffs Have Not Identified the Specific Language or Source of the Warranties

Defendants provided ample authority to support their position that Plaintiffs must plead specific language or the source of an express warranty, whereas Plaintiffs have provided no opposing authority. Opp. 64-65; Br. 48–49. Representations about

[23] Similar to New Jersey, numerous jurisdictions have interpreted "basis of the bargain" to mean that Plaintiffs must at least see or hear the alleged representation before it becomes a warranty. Others have required the more stringent standard of reliance, *i.e.*, an inducement of the purchase. *See* Second Charts 8. Although not all jurisdictions have elaborated on the "basis of the bargain" requirement, no jurisdiction adopting the UCC could find that a statement constituted an express warranty absent Plaintiff seeing or hearing that statement before or during the transaction.

the general safety or efficacy of VCDs do not create express warranties unless Plaintiffs also allege the representations were unqualified. Opp. 65; Br. 49.[24]

And, as with the breach of implied warranty claims, Plaintiffs' purported exceptions to privity are inapplicable.[25]

3. Plaintiffs Have Failed to Demonstrate Pre-Suit Notice

Plaintiffs' pre-suit letters only apply to a limited number of Plaintiffs and a limited subset of Defendants.[26] Opp. 66. Moreover, none of the letters were sent before the initial suits were filed. Plaintiffs also cite no authority—and make no distinction between states—supporting the proposition that a recall is sufficient to put Defendants on pre-suit notice of claims. To the contrary, a recall does not serve

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[24] As a matter of law, representations about the general safety or efficacy of a drug do not create express warranties unless Plaintiffs also demonstrate those representations were explicitly unqualified. Opp. 65; Br. 49.

[25] Plaintiffs argue for various inapplicable exceptions. Opp. 60–61. **Connecticut**: *Utica* only concerns horizontal, not vertical privity. The insured in that case *was* in vertical privity with the manufacturer. 778 F. Supp. 592, 592 (D. Conn. 1991); **Florida**: The *Aprigliano* case overstates the exception discussed in *Mesa v. BMW of N. Am., LLC*, 904 So.2d 450, 57–58 (Fla. Dist. Ct. App. 2005). As *Mesa* indicates, this exception only applies where the terms of a warranty explicitly extend to subsequent purchasers, which has not been alleged here; **Georgia**: The case Plaintiffs cite makes clear that the warranty only extends if the warranty explicitly applies to subsequent purchasers; **Illinois**: On the terms of the case cited by Plaintiffs, the manufacturer must give the warranty "directly" to the buyer, which is not at issue here; **Kentucky**: *Estate of Demoss* concerns a statutory claim, not a common law claim for express warranty; **Maryland**: Plaintiffs are not third-party beneficiaries; **Wisconsin**: The case cited by Plaintiffs does not state a rule for privity relating to economic loss, express warranty claims.

[26] These materials are extraneous to the Complaints and should not be considered. Plaintiffs must plead pre-suit notice.

as sufficient notice. *See Am. Fed'n of State Cty. & Mun. Emps. v. Ortho-McNeil-Janssen Pharm., Inc*., No. 08-5904, 2010 WL 891150, at *6 (E.D. Pa. Mar. 11, 2010); *see also Perona v. Volkswagen of Am., Inc*., 684 N.E.2d 859, 872 (Ill. App. Ct. 1997). Plaintiffs identify no authority indicating that this Court's direction to draft and file master complaints obviates the notice requirements of state law.

4. Plaintiffs' Magnuson-Moss Warranty Act Claims Fail

Plaintiffs do not address Defendants' argument that the MMWA is inapplicable where federal law controls the content of the alleged warranty. Opp. 54 n.12. Given this concession, the MMWA claims should be dismissed.

C. Plaintiffs Fail to Plead Unjust Enrichment Claims

Contrary to Plaintiffs' assertion that Defendants conflate "direct benefit" with the "direct ***conferral*** of that benefit," Opp. 74, Defendants' original chart clearly indicates that "direct benefit" means conferral.[27] Charts 50–51.[28]

Plaintiffs' arguments regarding adequate remedy at law and duplicative claims are also unavailing. Plaintiffs correctly state that they "are entitled to plead two or more statements of a claim or defense in the alternative," Opp. 72, but provide

[27] Plaintiffs cite one case for the proposition that the "direct" rule does not apply to written warranties, so Plaintiffs' argument should be limited to that jurisdiction. Opp. 73.

[28] Disputing the direct benefit requirement, Plaintiffs focus on outmoded law in Florida. Opp. 76. However, in 2017, the Florida Supreme Court stated "to prevail on an unjust enrichment claim, the plaintiff must *directly* confer a benefit to the defendant." *Kopel v. Kopel*, 229 So. 3d 812, 818 (Fla. 2017) (emphasis added).

no further argument as to why this court should not dismiss claims in the six states requiring an affirmative showing of an *absence* of an adequate remedy. Charts 49.

Plaintiffs further state that their claims are not duplicative because they focus on Defendants' purported "ill-gotten gains." Opp. 72–73. However, Plaintiffs fail to allege how the Manufacturing Defendants received any gains from Plaintiffs or to differentiate the unjust enrichment claims against Manufacturing Defendants from the other duplicative causes of action. As such, Plaintiffs' claims brought under the states that preclude unjust enrichment where there is an adequate remedy at law should be dismissed. *See* Charts 52–56.

D. Plaintiffs Fail to Plead Negligence Claims

Plaintiffs argue that it is inappropriate for a court to dismiss the ELMC's and MMMC's negligence claims on economic loss grounds where there *could be* issues of fact (*e.g.*, whether there is a special relationship or an independent duty) that *might* preclude application of some states' economic loss rules at this stage. Opp. 83. Plaintiffs only identify a handful of states even having such exceptions in their Appendix, leaving most of the economic loss rule states listed in Defendants' original chart unchallenged. *See* Charts 32–34. Even for states with exceptions to the economic loss rule, the mere possibility of an exception does not preclude dismissal at the Rule 12 stage. *See Reiff v. GAF Materials Corp.*, No 10-1142, 2010 WL 3081789, at *3 (E.D. Pa. Aug. 6, 2010). Plaintiffs fail to allege that any of these

exceptions apply. *See, e.g.*, *Winkworth v. Spectrum Brands, Inc.*, No. 19-1011, 2020 WL 3574687, at *7 (W.D. Pa. June 30, 2020) (dismissing negligence claims pursuant to the economic loss rule despite plaintiffs' argument that defendant owed an independent duty).

Plaintiffs also contend that "without doubt" they have adequately pleaded negligence claims against the Manufacturer Defendants, Opp. 78–80, yet they fail to allege that the asserted cGMP violations actually led to the presence of nitrosamines in Defendants' VCDs. *Id.* 79–80. Their claims thus lack proximate causation.

Moreover, Plaintiffs' suggestion that Defendants failed to conduct adequate tests ignores the many states that do not recognize such claims.[29]

E. Plaintiffs Fail to Plead Negligence *Per Se* Claims

Plaintiffs have conceded that: (1) Plaintiffs fail to allege they are within the protected class, as required for many states' negligence *per se* claims, Br. 41; Charts 29;[30] and (2) eleven states limit or do not recognize negligence *per se* claims. Br. 42–43; Charts 31. Accordingly, those claims should be dismissed.

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[29] *See, e.g.*, *Rodman v. Otsuka Am. Pharm., Inc.*, ---F. Supp. 3d---, 2020 WL 2525032, at *7 n.6 (N.D. Cal. May 18, 2020); *Baird v. Bayer Healthcare Pharm., Inc.*, No. 13-77, 2013 WL 5890253, at *2 (E.D. Ky. Oct. 31, 2013); *Skotak v. Tenneco Resins, Inc.*, 953 F.2d 909, 912 n.5 (5th Cir. 1992) (Texas law).

[30] Rather than showing how Plaintiffs fit within the class contemplated by state statutes, Plaintiffs argue consumers are within the class protected by the FDCA. Opp. 78 n.37. For reasons stated above, this claim is obviously preempted, and Plaintiffs did not allege consumers were a protected class in the Complaints.

F. Plaintiffs Fail to Plead Fraud Claims

Plaintiffs concede that actual knowledge of a statement's falsity is required to state a fraud claim. Opp. 83–84. Although Plaintiffs have claimed that the various Manufacturing Defendants failed to conduct adequate testing, keep proper records, or otherwise adhere to the law, *id.* 85–86, Plaintiffs have not alleged Defendants' actual knowledge of the contamination.

The Complaints fail to describe *how* the Manufacturer Defendants *knew* their valsartan was contaminated and *lied* about that contamination. *Id.* 86. Absent allegations of knowledge, Plaintiffs' fraud claims should be dismissed

G. The PIMC's And MMMC's Failure to Warn Claims Must Be Dismissed

The PIMC and MMMC do not plausibly allege that the Manufacturer Defendants knew or should have known about the alleged impurity. *See* Br. 41–42. Plaintiffs inexplicably argue that the "recall" serves as notice, as if Defendants have a duty to warn about products no longer sold to consumers. Opp. 90.

Plaintiffs' barebones allegations fall short of setting forth a viable claim against any Defendant. With respect to Defendant ZHP, the PIMC and MMMC contend, in a conclusory manner, that ZHP "failed to evaluate the potential effects that changes in the manufacturing process may have on the quality of its API." MMMC ¶ 199. Similarly, with respect to the allegations against Defendants Hetero Drugs and Hetero Labs, the PIMC and MMMC allege deviations from cGMP

standards, but fail to set forth ***prior*** knowledge of an alleged contamination. MMMC ¶¶ 206–218. The PIMC and MMMC make parallel allegations against Defendants Mylan and Aurobindo, setting forth purported inadequate cleaning protocols and improper recordkeeping, but fail to set forth the key contention that Defendants had knowledge of the existence of the alleged defect, or that the alleged defect posed a foreseeable risk of contamination with NDMA or NDEA, that gives rise to strict liability and a duty to warn. MMMC ¶¶ 232, 242, 248.[31] As to the other Manufacturer Defendants, the PIMC and MMMC contain no allegations whatsoever pointing to knowledge of any contamination of their VCDs with NDMA or NDEA, sufficient to give rise to strict liability and a duty to warn.

H. Plaintiffs Do Not Assert a Plausible Design Defect Claim

The Opposition contends Plaintiffs may allege multiple liability theories. Opp. 92–93. Defendants do not dispute that, but Plaintiffs fail to identify, any aspect of Defendants' design as defective, nor do they specify any deviation from the "FDA-approved" design. *See Bell v. Boehringer Ingelheim Pharm., Inc.*, No. 17-1153, 2018 WL 928237, at *5 (W.D. Pa. Feb. 15, 2018); Opp. 92–93.

[31] Plaintiffs' Opposition also completely ignores that their Strict Liability claims for Failure to Warn cannot proceed in states that reject strict liability. *See* Charts 28.

I. Plaintiffs' Medical Monitoring Claims Fail

Plaintiffs' arguments conflate requests for medical monitoring damages with independent causes of action. Opp. 97–99. Plaintiffs also misunderstand that their failure to allege injury in the MMMC precludes medical monitoring claims in certain states. *Id.* Defendants seek dismissal of medical monitoring claims in states requiring physical injury and in states that do not recognize independent medical monitoring causes of action regardless of injury. Br. 53–54; Charts 57–60.

The MMMC excludes individuals who have suffered actual harm, and seeks to represent a putative class of individuals with no symptoms, adverse effects, or illness, only a vague and indefinite potential for future harm. Most courts that have considered the issue have found claims of sub-cellular or genetic "injuries" without physical manifestations are not injuries. *See, e.g.*, *Ranier v. Union Carbide Corp.*, 402 F.3d. 608, 618–22 (6th Cir. 2005); *In re Berg Litig.*, 293 F.3d 1127, 1132–33 (9th Cir. 2002). Numerous cases cited in Defendants' medical monitoring charts recognize the injury distinction as dispositive. Charts 58–59.[32] Accordingly, Defendants request that this court dismiss all medical monitoring claims from the thirty-four states that either require a physical injury for a medical monitoring claim

[32] Plaintiffs' reliance on *Hardwick v. 3M Co*. is misplaced. Opp. 99. There the court only determined whether plaintiffs had adequately requested medical monitoring as relief, not whether plaintiffs could plead such relief as a cause of action.

or only recognize medical monitoring in the form of damages and not an independent cause of action. Charts 57–58, 60.

J. Plaintiffs Fail to Plead Derivative Claims or Punitive Damages

The Opposition concedes that the PIMC's wrongful death, survival, and loss of consortium claims are derivative claims that cannot survive if the underlying claims do not. Opp. 94. Accordingly, to the extent the PIMC's underlying claims do not survive dismissal, the derivative claims also cannot. As to punitive damages, Plaintiffs assert this Court should not decide the availability of punitive damages on a motion to dismiss, citing *Jones*. Opp. 94. In *Jones*, however, plaintiffs did not attempt to set out a separate count for punitive damages, as Plaintiffs have done here. *Jones v. Francis*, No. 13-4562, 2013 WL 5603848, at *1 (D.N.J. Oct. 11, 2013). That count should be dismissed.

V. THE COMPLAINTS FAIL TO STATE ANY CLAIMS FOR RELIEF AGAINST FDA LIAISONS

The Opposition fails to address the limited statutory responsibilities of FDA Liaison Defendants under 21 C.F.R. § 207.69(b). It also fails to identify ***any*** legal precedent holding an FDA liaison liable for a foreign establishment's product. Br. 58–59. Thus, FDA Liaisons' request for relief is proper.

Plaintiffs claim they have pleaded what ***each Defendant*** "did, and when, how, and why they did it." Opp. at 3. That is inaccurate. The Complaints (and Plaintiffs' Opposition) make only blanket assertions regarding FDA Liaison Defendants.

Opp. 104–105. Plaintiffs lump the liaisons in with their corporate affiliates without spelling out their specific conduct, let alone describing how the liaisons designed, manufactured, or distributed valsartan. *See, e.g.*, ELMC ¶¶ 13, 24, 33, 51, 60, 69; PIMC ¶¶ 37, 61-64, 81, 177, 362-365; MMMC ¶¶ 4, 23, 25. 32, 103, 104, 339–342.[33]

To the extent Plaintiffs purport to allege specific conduct, Opp. 104, bald assertions in the Complaints as to the FDA Liaisons being involved with the VCDs without factual allegations in support and misrepresentation of materials outside the pleadings[34] do not make the assertions entitled to the assumption of truth. *Santiago v. Warminster Tp.*, 629 F.3d 121, 131 (3d Cir. 2010) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 680 (2009)). The importance and viability of the FDA Liaisons' motion should not be lost in the myriad of issues and pages in this omnibus briefing. Critical review makes clear that dismissal is warranted as to Prinston, Hetero USA, and APUSA as set forth in the moving brief.

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[33] Vertical integration alone does not impute liability on FDA Liaisons. Plaintiffs are required to plead facts that demonstrate the manufacturing parent corporation demonstrated intrusive control over the subsidiary. *See In re Chocolate Confectionary Antitrust Litig.*, 674 F. Supp. 2d 580, 598 (M.D. Pa. 2009). No such facts have been pled.

[34] Plaintiffs' Opposition and the Complaints also misrepresent and impermissibly rely upon materials outside the pleadings. *See, e.g.*, Opp. 104 (incorrectly claiming that the FDA ARB recall website cited in the Complaints references Hetero USA when the citations in the Complaints are to recall announcements identifying HLL and Camber without ***any*** mention of Hetero USA).

CONCLUSION

The Manufacturer Defendants' Motion to Dismiss affords this Court the opportunity to simplify these proceedings greatly by eliminating facially insufficient and legally invalid claims. Plaintiffs can offer this Court no plausible explanation why it should entertain claims from Plaintiffs who lack a concrete injury-in-fact, or why it should force Defendants to defend claims in which they are not alleged to have committed any wrongs against any Plaintiff, or why it should permit claims to move forward that either cannot satisfy the requisite elements of their governing states' laws or are denied legal recognition outright. Eliminating improper parties and deficient claims promotes justice and efficiency by narrowing the scope of this MDL and reducing the needless costs and burdens associated with discovery and fact-finding on claims that cannot succeed. For these reasons, the Court should grant the Motion to Dismiss.

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Respectfully submitted,

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